# Anesthesia and Sedation.

NECESSITY, FUNCTION, AND CONFORMITY: KRS XXX.XXX requires the board to establish a reasonable schedule of fees, charges, and fines.

- Section 1. Definitions. In this regulation, the following terms have the meanings indicated.
  - (1) "Administration evaluation" means an evaluation by the Board or its designee to determine if an applicant for a permit demonstrates knowledge of management of emergencies and anesthesia techniques to a level that meets the requirements of this regulation.
  - (2) "Advanced Cardiac Life Support (ACLS)" means a certification that an individual has successfully completed an advanced cardiac life support course that meets or exceeds the standards set by the American Heart Association.
  - (3) "Anesthesia" means an artificially induced insensibility to pain usually achieved by the administration of gases or the use of drugs.
  - (4) "Anesthesia and sedation" means:
    - (a) Moderate sedation:
    - (b) Deep sedation; and
    - (c) General anesthesia.
  - (5) "Anxiolysis" means a drug-induced state, with or without nitrous oxide/oxygen to decrease anxiety, in which patients respond normally to tactile stimulation and verbal commands. Although cognitive function and coordination may be impaired, ventilatory and cardiovascular functions are maintained and require no assistance.
  - (6) "Board" means the Kentucky Board of Dentistry.
  - (7) "Certified registered nurse anesthetist" means a registered nurse who is currently certified to practice nurse anesthesia in Kentucky.
  - (8) "Deep sedation" means a drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully following repeated or painful stimulation. The ability to independently maintain ventilatory function may be impaired. Cardiovascular function is usually maintained.
  - (9) "Facility" means any location in which anesthesia or sedation is administered for the practice of dentistry.
  - (10) "Facility evaluation" means an on-site inspection by the Board or its designee to determine if a facility where the applicant proposes to provide anesthesia and sedation is adequately supplied, equipped, staffed, and maintained in a condition to support the provision of anesthesia and sedation services in a manner that meets the requirements of this regulation.
  - (11) "General anesthesia" means a drug-induced loss of consciousness during which patients are not arousable even by painful stimulation. The ability to independently maintain ventilatory function is often impaired. Patients often require assistance in maintaining a patent airway, and positive pressure ventilation may be required because of depressed spontaneous ventilation, drug-induced depression, or changes in neuromuscular function. Cardiovascular function may be impaired.
  - (12) "General anesthesia administration permit" means a permit that was issued by the Board before <u>July 15</u>, 2010, that authorized the dentist to whom the permit was issued to administer general anesthesia for the practice of dentistry.

- (13) "Incident" means dental treatment performed on a patient under moderate sedation, deep sedation, or general anesthesia with unforeseen complications.
- (14) "Moderate enteral sedation" means a drug-induced depression of consciousness through the gastrointestinal tract or oral mucosa during which patients respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation. No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained.
- (15) "Moderate parenteral sedation" means a drug-induced depression of consciousness that bypasses the gastrointestinal tract or oral mucosa during which patients respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation. No interventions are required to maintain a patent airway and spontaneous ventilation is adequate. Cardiovascular function is usually maintained.
- (16) "Moderate sedation" means a drug-induced depression of consciousness during which patients respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation. No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is maintained.
- (17) "Parenteral" means a technique of administration in which the drug bypasses the gastrointestinal tract, that is, through an intramuscular, intravenous, intranasal, submucosal, subcutaneous, or intraosseous technique.
- (18) "Conscious sedation administration permit" means a permit that was issued by the Board before July 15, 2010, that authorized the dentist to whom the permit was issued to administer parenteral sedation for the practice of dentistry.
- (19) "Pediatric Advanced Life Support (PALS)" means a certification that an individual has successfully completed a pediatric advanced life support course that meets or exceeds the standards set by the American Heart Association.
- (20) "Physician" means a physician, including a doctor of osteopathy, who holds a current license to practice medicine in Kentucky.
- (21) "Renewal evaluation" means an on-site inspection by the Board or its designee before the renewal of a permit to determine if a facility where the applicant proposes to provide anesthesia and sedation is adequately supplied, equipped, staffed, and maintained in a condition to support the provision of anesthesia and sedation services in a manner that meets the requirements of this regulation.
- (22) "Sedation" means the reduction of stress or excitement by the administration of a drug that has a soothing, calming, or tranquilizing effect.

# Section 2. Anxiolysis.

- (1) A permit is not required for a dentist to administer anxiolysis.
- (2) A dentist who intends to administer anxiolysis shall indicate the intent to administer anxiolysis in the patient's records.
- (3) A dentist who administers anxiolysis may not administer a dose that is inappropriate for a patient's:
  - (a) Age;
  - (b) Weight;
  - (c) Medical condition;
  - (d) Infirmities; or
  - (e) Other propensities.

- (4) Medications used to produce anxiolysis may not exceed current limits set by the manufacturer for unmonitored use by the individual.
- (5) A dentist who administers anxiolysis shall maintain a margin of safety and a level of consciousness that does not approach moderate sedation and other deeper states of sedation and general anesthesia.

#### Section 3. Classifications of Permits and Certificates.

- (1) The following permits shall be issued by the Board:
  - (a) Class I permit that authorizes a dentist to use a nonparenteral anesthetic technique to attain the level of moderate sedation;
  - (b) Class II permit that authorizes a dentist to use:
    - 1. A parenteral anesthetic technique to attain the level of moderate sedation; and
    - 2. Any procedure allowed with a Class I permit;
  - (c) Class III permit that authorizes a dentist to use:
    - 1. An anesthetic technique to attain the level of deep sedation or general anesthesia; and
  - 2. Any procedure allowed under either a Class I permit or a Class II permit; and (d) Class III dental school facility permit issued to a dental school that allows a dentist who holds the appropriate Class I, Class II, or Class III permit to administer anesthesia or sedation in a dental school recognized by the Commission on Dental Accreditation (CODA) or its successor organization.
- (2) The following certificates shall be issued to qualified dentists by the Board:
  - (a) Certificate to allow a physician or another dentist to administer anesthesia and sedation, which allows a physician or another dentist to administer anesthesia and sedation to a patient at a specific practice location;
  - (b) Certificate to allow a dentist to treat a patient at a practice location other than their own at which anesthesia and sedation is administered, which allows a dentist to treat a patient at a practice location other than their own in which anesthesia and sedation is administered; and
  - (c) Certificate to allow a certified registered nurse anesthetist to administer anesthesia and sedation, which allows a certified registered nurse anesthetist to administer anesthesia and sedation to a patient at a specific practice location.
- Section 4. Permit Required. After <u>July 15</u>, 2010, a dentist may not administer an anesthetic technique in order to attain a level beyond anxiolysis for the practice of dentistry unless the dentist holds an appropriate Class I, II, or III permit issued by the Board.

### Section 5. Location Requirement.

- (1) A dentist shall advise the Board of the name and address of each location where the dentist wishes to administer anesthesia and sedation by submitting the "Anesthesia and Sedation Permit Location Notification Form".
- (2) A dentist may not administer anesthesia and sedation unless the dentist has obtained the appropriate permit for each location.
- (3) A dentist shall advise the Board of each location at which the dentist has ceased to administer anesthesia and sedation by submitting the "Anesthsia and Sedation Permit Location Notification Form".

- (4) The Board shall keep a record of:
  - (a) Each location for which a dentist has been granted a permit to administer anesthesia and sedation; and
  - (b) Each location at which a dentist has ceased to administer anesthesia and sedation.

### Section 6. Qualifications for Obtaining a Permit.

- (1) Because sedation is a continuum, it is not always possible to predict how an individual patient will respond. Therefore, practitioners intending to produce a given level of sedation shall be able to recover patients whose level of sedation becomes deeper than initially intended. Individuals administering moderate enteral sedation or moderate parenteral sedation shall be able to recover patients who enter a state of deep sedation or general anesthesia, while those administering deep sedation shall be able to recover patients who enter a state of general anesthesia. Training and evaluation guidelines shall reflect this concern.
- (2) In addition to the requirements outlined in this regulation, in order to obtain a permit, a dentist shall also meet the requirements outlined in Sections 7, 8, and 9 of this regulation.
- (3) A permit may be issued to a dentist authorizing the use of moderate sedation, deep sedation, or general anesthesia at a specific practice location.
- (4) Class I: Moderate Enteral Sedation Permit. To qualify for a Class I permit, an applicant shall successfully complete:
  - (a) A Board-approved course of instruction that documents training of at least 24 hours of didactic education plus 20 clinically oriented experiences that provide competency in oral and combination inhalation-oral moderate sedation; or
  - (b) A CODA-accredited postdoctoral training program that affords comprehensive and appropriate training necessary to administer and manage moderate enteral sedation.
- (5) Clinically oriented experiences referred to in Subsection (4)(a) of this section may include:
  - (a) Supervised administration;
  - (b) Observations of videotaped patients undergoing oral or combination inhalationoral moderate sedation; or
  - (c) Human simulation.
- (6) In addition to the requirements outlined in Subsection (4) of this section, an applicant for a Class I permit shall:
  - (a) Hold current certification in either ACLS or PALS-or successfully complete a course approved by the Board that provides instruction on medical emergencies and airway management;
  - (b) Receive a successful evaluation by the Board or the Board's designee;
  - (c) Provide an affidavit to the Board indicating whether the applicant has ever treated a patient under deep sedation or general anesthesia with an incident; and
  - (d) Submit any other pertinent documents or information requested by the Board.

- (7) An affidavit provided to the Board under Subsection (6)(c) of this section, which indicates that the applicant has treated a patient under deep sedation or general anesthesia with an incident, shall include at least the following:
  - (a) The date of the incident;
  - (b) The name, age, and address of the patient;
  - (c) The patient's original complete dental records;
  - (d) The name and license number of the licensee and the name and address of all other persons present during the incident;
  - (e) The address where the incident took place;
  - (f) The preoperative physical condition of the patient;
  - (g) The type of anesthesia and dosages of drugs administered to the patient;
  - (h) The techniques used in administering the drugs;
  - (i) Any adverse occurrence including:
    - 1. The patient's signs and symptoms;
    - 2. The treatments instituted in response to adverse occurrences;
    - 3. The patient's response to the treatment; and
    - 4. The patient's condition on termination of any procedures undertaken; and
  - (j) A narrative description of the incident including approximate times and evolution of symptoms.
- (8) Class II: Moderate Parenteral Sedation Permit. To qualify for a Class II permit, an applicant shall successfully complete:
  - (a) A Board-approved course of instruction that documents training of at least 60 hours of didactic instruction plus management of at least 20 patients per participant in moderate parenteral sedation techniques; or
  - (b) A CODA-accredited postdoctoral training program that affords comprehensive and appropriate training necessary to administer and manage moderate parenteral sedation.
- (9) In addition to the requirements outlined in Subsection (8) of this section, an applicant for a Class II permit shall:
  - (a) Hold current certification in either ACLS or PALS;
  - (b) Receive a successful evaluation by the Board or the Board's designee;
  - (c) Provide an affidavit to the Board indicating whether the applicant has ever treated a patient under deep sedation or general anesthesia with an incident; and
  - (d) Submit any other pertinent documents or information requested by the Board.
- (10) An affidavit provided to the Board under Subsection (9)(c) of this section, which indicates that the applicant has treated a patient under deep sedation or general anesthesia with an incident, shall include the information contained in Subsection (7) of this section.
- (11) Class III: Deep Sedation and General Anesthesia Permit. To qualify for a Class III permit, an applicant shall have successfully completed:
  - (a) An advanced training program in anesthesia and related subjects beyond the undergraduate dental curriculum that is approved by the Board; or
  - (b) A CODA-accredited postdoctoral training program that affords comprehensive and appropriate training necessary to administer and manage deep sedation and general anesthesia.
- (12) In addition to the requirements outlined in Subsection (11) of this section, an applicant for a Class III permit shall:

- (a) Hold current certification in either ACLS or PALS;
- (b) Receive a successful evaluation by the Board or its designee;
- (c) Provide an affidavit to the Board indicating whether the applicant has ever treated a patient under deep sedation or general anesthesia with an incident; and
- (d) Submit any other pertinent documents or information requested by the Board.
- (13) An affidavit provided to the Board under Subsection (12)(c) of this section, which indicates that the applicant has treated a patient under deep sedation or general anesthesia with an incident, shall include the information contained in Subsection (7) of this section.

#### Section 7. Administration Evaluation.

- (1) Class I Permit. To qualify for a Class I permit, the dentist who will perform the administration shall pass:
  - (a) An office inspection evaluation;
  - (b) A clinical evaluation consistent with the age level of the patients treated by the dentist:
  - (c) An evaluation of the dentist to safely administer sedation techniques; and
  - (d) An evaluation of the ability of the dentist to effectively respond to sedation related emergencies.
- (2) The clinical evaluation required in Subsection (1) of this section shall require the participation of the office staff.
- (3) The clinical evaluation shall include evaluating treatment of at least the following:
  - (a) Laryngospasm;
  - (b) Foreign body airway obstruction;
  - (c) Emesis and aspiration;
  - (d) Acute allergic reaction;
  - (e) Bronchospasm;
  - (f) Angina;
  - (h) Conditions requiring advanced cardiac life support, including:
    - 1. Bradycardia;
    - 2. Tachycardia;
    - 3. Ventricular fibrillation; and
    - 4. Cardiac arrest;
  - (i) Hypotension;
  - (j) Hypertension;
  - (k) Seizure;
  - (1) Syncope; and
  - (m) Venipuncture complications.
- (4) Class II or Class III Permit.
  - (a) To qualify for a Class II or Class III permit, the dentist who will perform the administration shall pass an administration evaluation that consists of an office inspection and clinical evaluation.
  - (b) This clinical evaluation shall:
    - 1. Require the participation of the clinical office staff; and
    - 2. Evaluate the technical competency of the dentist to:
      - a. Safely administer moderate parenteral sedation, deep sedation, or general anesthesia; and

- b. Effectively respond to anesthesia related emergencies.
- (5) The clinical evaluation required by Subsection (4) of this section shall include evaluating the treatment of at least the following:
  - (a) Laryngospasm;
  - (b) Foreign body airway obstruction;
  - (c) Emesis and aspiration;
  - (d) Acute allergic reaction;
  - (e) Bronchospasm;
  - (f) Angina;
  - (g) Conditions requiring advanced cardiac life support, including:
    - 1. Bradycardia;
    - 2. Tachycardia;
    - 3. Ventricular fibrillation; and
    - 4. Cardiac arrest;
  - (h) Hypotension;
  - (i) Hypertension;
  - (j) Seizure;
  - (k) Syncope; and
  - (1) Venipuncture complications.

Section 8. Facility Evaluation. In addition to the requirements outlined in Section 7 of this regulation, for a dentist to obtain a Class I, Class II, or Class III permit, each facility in which the dentist wishes to administer an anesthesia technique shall pass a facility evaluation in order to attain:

- (1) A level beyond anxiolysis;
- (2) Moderate enteral sedation;
- (3) Moderate parenteral sedation; or
- (4) Deep sedation and general anesthesia.

Section 9. Facility Evaluation Criteria.

- (1) To qualify for a permit, the facility and the applicant shall pass an evaluation of facility equipment, medications, and clinical records to include at least the following:
  - (a) Oxygen and gas delivery system, backup system fail-safe;
  - (b) Gas storage facility;
  - (c) Safety indexed gas system;
  - (d) Suction and backup system;
  - (e) Auxiliary lighting system;
  - (f) Suitability of operating room:
    - 1. Size;
    - 2. Lighting;
    - 3. Communications; and
    - 4. EMT accessibility:
  - (g) Recovery area, including oxygen, suction, and visual and electronic monitoring, which may include the operating room;
  - (h) Appropriate emergency drugs;
  - (i) Nonexpired drugs;

- (j) Appropriate devices to maintain an airway with positive pressure ventilation;
- (k) Preoperative medical history and physical evaluation form;
- (l) Anesthesia records, including monitoring and discharge records;
- (m) Monitoring equipment, including pulse oximeter and blood pressure monitoring;
- (n) Electrocardiogram (EKG), Class II and Class III permits;
- (o) Anesthesia and monitoring equipment to ensure they are in proper working order;
- (p) Defibrillator or automated external defibrillator (AED) for adult patients;
- (q) Capnograph and temperature measuring device for the intubated patient receiving general anesthesia; and
- (r) For deep sedation or general anesthesia in pediatric patients:
  - 1. A precordial stethoscope;
  - 2. A pretracheal stethoscope; or
  - 3. A capnograph.
- (2) In addition to the requirements outlined in Subsection (1) of this section, to qualify for a permit, the dentist who will perform the administration and the dentist's staff shall be present in the operatory during the evaluation.

# Section 10. Exceptions.

- (1) A dentist who has passed an administration and facility evaluation for a Class I, Class II, or Class III permit may receive a like permit for another facility or facilities if:
  - (a) The dentist holds an active Class I, Class II, or Class III permit for which the dentist has passed an administration and facility evaluation; and
  - (b) Each facility for which the dentist seeks another permit has at least one dentist who has passed an administration and facility evaluation for a like permit at that location within 2 years of the date of application for the additional permit.
- (2) Alternatively, a dentist who has passed an administration and facility evaluation for a Class I, Class II, or Class III permit may receive a like permit for another facility or facilities if:
  - (a) The dentist holds an active Class I, Class II, or Class III permit for which the dentist has passed an administration and facility evaluation; and
  - (b) The dentist seeking the additional permit:
    - 1. Is present during a facility evaluation at which the dentist and the dentist's staff pass a facility evaluation; and
    - 2. Passes an evaluation, appropriate for the permit level, that includes simulated management of emergencies with the participation of the clinical office staff trained to handle emergencies.
- (3) In addition to the requirements of Subsections (1) and (2) of this section, the dentist seeking the additional permit or permits shall:
  - (a) Submit to the Board an "Application for a Sedation or Anesthesia Permit"; and
  - (b) Pay the fee required by administrative regulation.

### Section 11. Inducing a Level of Sedation for a Patient.

- (1) Administration of moderate enteral sedation, moderate parenteral sedation, deep sedation, or general anesthesia to a patient requires at least the following appropriately trained individuals:
  - (a) The treating dentist;
  - (b) An individual trained and competent in basic life support or its equivalent to assist the treating dentist; and
  - (c) Another individual trained and competent in basic life support or its equivalent in close proximity to assist if needed.
- (2) A dentist administering moderate enteral sedation, moderate parenteral sedation, deep sedation, or general anesthesia to a patient:
  - (a) May not leave the site until the patient:
    - 1. Is conscious;
    - 2. Is spontaneously breathing;
    - 3. Has stable vital signs;
    - 4. Is ambulatory with assistance; and
    - 5. Is under the care of a responsible adult; and
  - (b) May not induce a second patient until the first patient:
    - 1. Is conscious;
    - 2. Is spontaneously breathing;
    - 3. Has stable vital signs;
    - 4. Is ambulatory with assistance; and
    - 5. Is under the care of a responsible adult.
- (3) A treating dentist who allows a physician, another dentist, or certified registered nurse anesthetist to administer moderate enteral sedation, moderate parenteral sedation, deep sedation, or general anesthesia under Regulation .30, .31, or .32 of this regulation shall ensure that the physician, dentist, or certified registered nurse anesthetist does not leave the site until the patient:
  - (a) Is conscious:
  - (b) Is spontaneously breathing;
  - (c) Has stable vital signs;
  - (d) Is ambulatory with assistance; and
  - (e) Is under the care of a responsible adult.
- (4) A treating dentist who allows a physician, another dentist, or certified registered nurse anesthetist to administer moderate sedation, deep sedation, or general anesthesia shall ensure that the physician, dentist, or certified registered nurse anesthetist does not induce a second patient until the first patient:
  - (a) Is conscious;
  - (b) Is spontaneously breathing;
  - (c) Has stable vital signs;
  - (d) Is ambulatory with assistance; and
  - (e) Is under the care of a responsible adult.

Section 12. General Anesthesia and <u>Conscious</u> Sedation <u>Administration</u> Permits in Existence on July 15, 2010.

- (1) A dentist who held a current general anesthesia administration permit on <u>July 15</u>, 2010, may continue to administer anesthesia and sedation under the general anesthesia administration permit until the expiration of the permit only as provided in this section of this regulation.
- (2) A dentist who held a current <u>conscious</u> sedation administration permit on <u>July 15</u>, 2010, may continue to administer moderate parenteral sedation under the <u>conscious</u> sedation <del>administration</del> permit until the expiration of the permit only as provided in this section of this regulation.
- (3) A dentist who held a current general anesthesia administration permit on <u>July 15</u>, 2010, may administer anesthesia and sedation under the general anesthesia administration permit, consistent with a Class III permit, only in a facility <u>which has previously been inspected by the Board.for which the dentist holds a current general anesthesia facility permit.</u>
- (4) A dentist who held a current general anesthesia administration permit on July 15, 2010, and who wishes to administer general anesthesia in a facility which has not been previously inspected by the Board for which the dentist does not hold a general anesthesia facility permit shall apply for and be issued a Class III permit for that site in accordance with Sections 5 through 9 of this regulation.
- (5) A dentist who held a current <u>conscious</u> sedation <u>administration</u> permit on <u>July 15</u>, 2010, may administer parenteral sedation under the <u>conscious</u> sedation <u>administration</u> permit consistent with a Class II permit, only in a facility <u>which has previously been inspected by the Board.</u> for which the dentist holds a current parenteral sedation facility <u>permit.</u>
- (6) A dentist who held a current <u>conscious</u> sedation <u>administration</u> permit on <u>July 15</u>, 2010, and who wishes to administer parenteral sedation at a facility <u>which has not been previously inspected by the Board for which the dentist does not hold a parenteral sedation facility permit, shall apply for and be issued a Class II permit for that site in accordance with Sections 5 through 9 of this regulation.</u>
- (7) A dentist whose general anesthesia administration permit has expired may not administer general anesthesia unless the dentist holds a Class III permit issued by the Board.
- (8) A dentist whose <u>conscious</u> sedation <u>administration</u> permit has expired may not administer parenteral sedation unless the dentist holds a Class II permit issued by the Board.
- Section 13. Conversion of General Anesthesia and <u>Conscious</u> Sedation <u>Administration</u> Permits in Existence on <u>July 15</u>, 2010.
  - (1) All general anesthesia and conscious sedation permits issued by the Board prior to July 15, 2010 will expire with the holder's dental license.
  - (2) <u>During the license renewal process</u>, general anesthesia <u>administration</u> permit <u>holders</u> <u>may</u> convert the general anesthesia <u>administration</u> permit to a Class III permit.
  - (3) <u>During the license renewal process, conscious</u> sedation <u>administration</u> permit <u>holders may convert the conscious</u> sedation <u>administration</u> permit to a Class I or Class II permit.
  - (4) A dentist who held a current general anesthesia administration permit on <u>July 15</u>, 2010, and who wishes to receive a Class III permit for a location which has previously

been inspected by the Board, may receive a Class III permit for that location if the applicant:

- (a) <u>Submits a completed and signed "Application for Renewal of a Sedation or</u> Anesthesia Permit";
- (b) Pays the renewal fee required by administrative regulation;
- (c) Provides an affidavit to the Board indicating whether the applicant, since the issuance of the original general anesthesia administration permit, has treated a patient under deep sedation or general anesthesia with an incident;
- (d) Provides evidence satisfactory to the Board that the applicant meets the continuing education requirements outlined in Section 25 of this regulation; and
- (e) Submits any other pertinent documents or information requested by the Board.
- (5) An affidavit provided to the Board under Subsection (4)(c) of this section, which indicates that the applicant has treated a patient under deep sedation or general anesthesia with an incident, shall include the information contained in Section 6(7) of this regulation.
- (6) A dentist who held a current <u>conscious</u> sedation <u>administration</u> permit on <u>July 15</u>, 2010, and who wishes to receive a <u>Class I or</u> Class II permit for <u>a location which has already been inspected by the Board</u>, may receive a <u>Class I or</u> Class II permit for that location if the applicant:
  - (a) <u>Submits a completed and signed "Application for Renewal of a Sedation or</u> Anesthesia Permit";
  - (b) Pays the renewal fee required by administrative regulation; and
  - (c) Provides an affidavit to the Board indicating whether the applicant, since the issuance of the original <u>conscious</u> sedation <del>administration</del> permit, has treated a patient under deep sedation or general anesthesia with an incident;
  - (d) Provides evidence satisfactory to the Board that the applicant meets the continuing education requirements outlined in Section 25 of this regulation; and
  - (e) Submits any other pertinent documents or information requested by the Board.
- (7) An affidavit provided to the Board under Subsection (6)(c) of this section, which indicates that the applicant has treated a patient under deep sedation or general anesthesia with an incident, shall include the information contained in Section (6)(7) of this regulation.

Section 14. Compliance for Dentists with General Anesthesia and <u>Conscious</u> Sedation <u>Administration</u> Permits in Existence on <u>July 15</u>, 2010. A dentist with a general anesthesia <u>administration</u> permit or a <u>conscious</u> sedation <u>administration</u> permit in existence on <u>July 15</u>, 2010, shall comply with Sections 11, 22, 23, 26, 27, 28, and 30 of this regulation.

Section 15. Issuance and Expiration of Class I, Class II, and Class III Permits.

- (1) To apply to obtain a permit, an applicant shall:
  - (a) Submit to the Board an "Application for a Sedation or Anesthesia Permit";
  - (b) Pay the fee required by administrative regulation; and
  - (c) Provide evidence satisfactory to the Board that the applicant meets the qualifications for a Class I, Class II, or Class III permit.
- (2) The Board may issue a Class I, Class II, or Class III permit to an applicant for a specific practice location after the Board's review of:

- (a) The applicant's application and accompanying affidavit;
- (b) The applicant's qualifications;
- (c) The applicant's administration evaluation;
- (d) The applicant's facility evaluation; and
- (e) Any other pertinent documents or information including, but not limited to, patient complaints that may affect the applicant's ability to safely and effectively administer anesthesia and sedation.
- (3) A permit expires on December 31 of the odd numbered year following the effective date of the permit.

#### Section 16. Renewal of Class I and Class II Permits.

- (1) Before a Class I or Class II permit expires, an applicant may apply to renew the permit for an additional two (2) year term if the applicant:
  - (a) Submits to the Board an "Application for Renewal of a Sedation or Anesthesia Permit";
  - (b) Pays the renewal fee required by administrative regulation;
  - (c) Provides an affidavit to the Board indicating whether the applicant, since the issuance of the original permit or renewal, whichever is later, has treated a patient under deep sedation or general anesthesia with an incident;
  - (d) Provides evidence satisfactory to the Board that the applicant meets the continuing education requirements outlined in Section 25 of this regulation; and
  - (e) Submits any other pertinent documents or information requested by the Board.
- (2) An affidavit provided to the Board under Subsection (1)(c) of this section, which indicates that the applicant has treated a patient under deep sedation or general anesthesia with an incident, shall include the information contained in Section (6)(7) of this regulation.
- (3) The Board may issue a renewal of a Class I or Class II permit to an applicant for a specific practice location after the Board's review of:
  - (a) The applicant's renewal application and accompanying affidavit;
  - (b) The applicant's qualifications; and
  - (c) Any other pertinent documents or information, including, but not limited to, patient complaints that may affect the applicant's ability to safely and effectively administer anesthesia and sedation.

#### Section 17. Renewal of Class III Permits.

- (1) Before a Class III permit expires, an applicant may apply to renew the permit for an additional two (2) year term if the applicant:
  - (a) Submits to the Board an "Application for Renewal of a Sedation or Anesthesia Permit";
  - (b) Pays the renewal fee required by administrative regulation;
  - (c) Provides an affidavit to the Board indicating whether the applicant, since the issuance of the original permit or renewal, whichever is later, has treated a patient under deep sedation or general anesthesia with an incident;
  - (d) Provides evidence satisfactory to the Board that the applicant meets the continuing education requirements outlined in Regulation .28 of this chapter; and
  - (e) Submits any other pertinent documents or information requested by the Board.

- (2) An affidavit provided to the Board under Subsection (1)(c) of this section, which indicates that the applicant has treated a patient under deep sedation or general anesthesia with an incident, shall include the information contained in Section (6)(7) of this regulation.
- (3) The Board may issue a renewal of a Class III permit to an applicant for a specific practice location after the Board's review of:
  - (a) The applicant's renewal application and accompanying affidavit;
  - (b) The applicant's qualifications;
  - (c) The renewal evaluation; and
  - (d) Any other pertinent documents or information, including, but not limited to, patient complaints that may affect the applicant's ability to safely and effectively administer anesthesia and sedation.

### Section 18. Class III Dental School Facility Permit.

- (1) After <u>July 15</u>, 2010, a dentist may not administer anesthesia or sedation for the practice of dentistry in a CODA-accredited dental school unless the dental school holds a Class III dental school facility permit.
- (2) A dental school that applies for a Class III dental school facility permit shall pass an on-site facility evaluation by the Board or its designee as specified in Section 9 of this regulation.

# Section 19. Issuance and Expiration of Class III Dental School Facility Permits.

- (1) To obtain a dental school Class III facility permit a CODA-accredited dental school shall:
  - (a) Submit to the Board an "Application for a Class III Dental School Facility Anesthesia Permit";
  - (b) Pay the fee set by administrative regulation; and
  - (c) Provide evidence satisfactory to the Board that the dental school meets the qualifications for a Class III dental school facility permit.
- (2) A Class III dental school facility permit shall expire on December 31 of the odd numbered year following the effective date of the permit.
- Section 20. Renewal of Class III Dental School Facility Permits. Before a Class III dental school facility permit expires, the dental school may renew the permit for an additional two (2) year term if the dental school:
  - (1) Submits to the Board an "Application for Renewal of a Class III Dental School Facility Anesthesia Permit"; and
  - (2) Pays the renewal fee required by administrative regulation.

## Section 21. Dental School's Required Notice to Board.

- (1) A dental school that holds a Class III Dental School Facility Permit shall advise the Board of any additional locations it has opened since the issuance or the renewal of its original permit.
- (2) This notice shall be provided to the Board in writing no later than 30 days before the opening of the additional location.

- (3) A dentist may not administer anesthesia or sedation for the practice of dentistry in an additional location unless the school holds a Class III dental school facility permit for the additional location.
- (4) A dental school that applies for a Class III dental school facility permit for an additional location shall pass an on-site facility evaluation by the Board or its designee as contained in Section 9 of this regulation.

Section 22. Facility Records. All facilities including a dental school that holds a Class III dental school facility permit shall maintain for 5 years for inspection by the Board:

- (1) The name of each dentist who has administered anesthesia or sedation; and
- (2) The license number of each dentist who has administered anesthesia or sedation.

### Section 23. Unannounced Inspection Visits.

- (1) The Board or its designee may conduct, during reasonable business hours, unannounced inspection visits of any dental office or facility for which a dentist holds:
  - (a) A Class I permit;
  - (b) A Class II permit;
  - (c) A Class III permit;
  - (d) A general anesthesia administration permit; or
  - (e) A conscious sedation administration permit.
- (2) During inspection visits, inspectors shall:
  - (a) Examine the facility's equipment to determine if it is in proper working order;
  - (b) Determine if appropriate emergency drugs are present; and
  - (c) Determine if emergency drugs are nonexpired.
- (3) Dentists and their employees and staff shall cooperate with the inspectors.
- (4) Within 30 days of the conclusion of the inspection, the inspectors shall submit a written report of the inspection to:
  - (a) The Board; and
  - (b) Each dentist who holds the:
    - 1. Class I permit;
    - 2. Class II permit;
    - 3. Class III permit;
    - 4. General anesthesia administration permit; or
    - 5. Parenteral sedation administration permit.

### Section 24. Facility Owner or Operator.

- (1) The owner or operator of a facility may not permit an individual to administer anesthesia or sedation unless the individual is qualified to do so under this chapter.
- (2) The owner or operator of a facility shall ensure that the facility:
  - (a) Remains properly equipped in accordance with Section 9(1) of this regulation; and
  - (b) Remains properly staffed in accordance with Section 11(1) of this regulation.
- (3) In addition to the requirements contained in Subsection (2) of this section, the owner or operator of a facility shall ensure that the facility has:
  - (a) Appropriate nonexpired emergency drugs; and
  - (b) Appropriate nonexpired drugs.

- (4) After an opportunity for a hearing, the Board may take disciplinary action against a dentist under KRS xxx.xxx, if the Board finds that:
  - (a) The dentist violates any provisions of this chapter; or
  - (b) The facility is inadequate under the provisions of this chapter.
- (5) Failure to comply with this chapter constitutes unprofessional conduct and may constitute other violations of law.

# Section 25. Continuing Education Requirements for Renewal of a Permit.

- (1) An applicant who seeks renewal of a Class I, Class II, or Class III permit shall:
  - (a) Complete not less than 4 hours of clinical continuing education related to sedation or anesthesia in a classroom setting during the two (2) year term of the permit; and
  - (b) Maintain cardiopulmonary resuscitation (CPR) certification which meets or exceeds the guidelines set by the American Heart Association.
- (2) In addition to the requirements outlined in Subsection (1) of this section, an applicant for the renewal of a Class I permit shall do one of the following:
  - (a) Maintain Advanced Cardiac Life Support (ACLS) certification;
  - (b) Maintain Pediatric Advanced Life support certification (PALS); or
  - (c) Complete a Board-approved course that provides instruction on medical emergencies and airway management.
- (3) In addition to the requirements outlined in Subsection (1) of this section, an applicant for the renewal of a Class II or Class III permit shall either:
  - (a) Maintain Advanced Cardiac Life Support (ACLS) certification; or
  - (b) Maintain Pediatric Advanced Life Support (PALS) certification.

Section 26. Transfer of Permits Prohibited. A Class I, Class II, or Class III permit may not be transferred to another person or location.

Section 27. Administration by Physicians or Dentists at the Site of a Treating Dentist.

- (1) A treating dentist who wishes to allow a physician or another dentist to administer anesthesia and sedation to a patient at a specific practice location shall receive a certificate from the Board before allowing a physician or another dentist to administer anesthesia and sedation at that location.
- (2) To apply for a certificate to allow a physician or another dentist to administer anesthesia and sedation:
  - (a) A treating dentist shall:
    - 1. Submit an "Application to Allow a Physician or Another Dentist to Administer Anesthesia or Sedation";
    - 2. Possess either a Class I, Class II, or Class III permit;
    - 3. Provide an affidavit to the Board indicating whether the applicant has ever treated a patient under deep sedation or general anesthesia with an incident;
    - 4. Submit any other pertinent documents or information requested by the Board; and
    - 5. Pay the fee required by administrative regulation; or
  - (b) A treating dentist shall:
    - 1. Submit an "Application to Allow a Physician or Another Dentist to Administer Anesthesia or Sedation";

- 2. Provide documentation to the Board that the treating dentist has completed a Board-approved training program where the treating dentist received competent training in treating patients under:
  - a. Moderate enteral sedation and airway management;
  - b. Moderate parenteral sedation and airway management;
  - c. Deep sedation and airway management; or
  - d. General anesthesia and airway management;
- 3. Provide an affidavit to the Board indicating whether the applicant has ever treated a patient under deep sedation or general anesthesia with an incident;
- 4. Submit any other pertinent documents or information requested by the Board; and
- 5. Pay the fee required by administrative regulation.
- (3) An affidavit provided to the Board under Subsection (2)(a) or (2)(b) of this section, which indicates that the applicant has treated a patient under deep sedation or general anesthesia with an incident, shall include the information contained in Section (6)(7) of this regulation.
- (4) In addition to the requirements contained in Subsections (1) through (3) of this section, a treating dentist who applies for a certificate to allow a physician or another dentist to administer anesthesia and sedation to a patient shall:
  - (a) Maintain either a Class I, Class II, or Class III permit for the administration site; and
  - (b) Maintain facility equipment in the facility consistent with a Class III permit as outlined in Section 9(1) of this regulation.
- (4) The Board may issue a certificate to a dentist to allow a physician or another dentist to administer anesthesia and sedation after the Board's review of:
  - (a) The applicant's application and accompanying affidavit;
  - (b) The applicant's qualifications;
  - (c) The applicant's patient records; and
  - (d) Any other pertinent documents or information including, but not limited to, patient complaints which may affect the applicant's ability to safely and effectively treat patients under anesthesia and sedation.
- (5) A certificate issued to a treating dentist to allow a physician or another dentist to administer anesthesia and sedation at a specific location shall expire on December 31 of the odd numbered year following the effective date of the certificate.
- (6) A dentist who administers anesthesia or sedation pursuant to Subsection (1) of this section shall maintain the appropriate permit for the administration site.
- (7) Before the certificate expires, an applicant may apply to renew the certificate for an additional two (2) year term if the applicant submits to the Board:
  - (a) An "Application for Renewal of a Certificate to Allow a Physician or Another Dentist to Administer Anesthesia or Sedation";
  - (b) An affidavit indicating whether the applicant, since the issuance of the original certificate or renewal, whichever is later, has treated a patient under deep sedation or general anesthesia with an incident;
  - (c) The fee required by administrative regulation; and
  - (d) Any other pertinent documents or information requested by the Board.

- (8) An affidavit provided to the Board under Subsection (7)(b) of this section, which indicates that the applicant has treated a patient under deep sedation or general anesthesia with an incident, shall include the information contained in Section (6)(7) of this regulation.
- (9) The Board may issue a renewal certificate to a dentist to allow a physician or another dentist to administer anesthesia and sedation after the Board's review of:
  - (a) The applicant's application and accompanying affidavit;
  - (b) The applicant's qualifications; and
  - (c) Any other pertinent documents or information including but not limited to patient complaints which may affect the applicant's ability to safely and effectively treat patients under anesthesia and sedation.
- Section 28. Certification of a Dentist Providing Treatment Outside the Dentist's Location.
  - (1) A treating dentist who treats a patient at a practice location other than the dentist's own location, at which anesthesia and sedation are administered to the patient, shall receive a certificate from the Board before treating the patient.
  - (2) To apply for a certificate to treat a patient at a practice location other than the dentist's own location, at which anesthesia and sedation are administered to the patient:
    - (a) A treating dentist shall:
      - 1. Submit an "Application to Provide Treatment Outside the Dentist's Location";
      - 2. Possess a Class I, Class II, or Class III permit;
      - 3. Provide an affidavit to the Board indicating whether the applicant has ever treated a patient under deep sedation or general anesthesia with an incident;
      - 4. Submit any other pertinent documents or information requested by the Board; and
      - 5. Pay the fee required by administrative regulation; or
    - (b) A treating dentist shall:
      - 1. Submit an "Application to Provide Treatment Outside the Dentist's Location";
      - 2. Provide documentation to the Board that the treating dentist has completed a Board-approved training program where the treating dentist received competent training in treating patients under:
        - a. Moderate enteral sedation and airway management;
        - b. Moderate parenteral sedation and airway management;
        - c. Deep sedation and airway management; or
        - d. General anesthesia and airway management;
      - 3. Provide an affidavit to the Board indicating whether the applicant has ever treated a patient under deep sedation or general anesthesia with an incident;
      - 4. Submit any other pertinent documents or information requested by the Board; and
      - 5. Pay the fee required by administrative regulation.
  - (3) An affidavit provided to the Board under Subsection (2)(a) or (2)(b) of this section, which indicates that the applicant has treated a patient under deep sedation or general anesthesia with an incident, shall include the information contained in Section (6)(7) of this regulation.

- (4) In addition to the requirements contained in Subsections (1) through (3) of this section, a treating dentist who applies for a certificate shall maintain a Class I, Class II, or Class III permit for an administration site in the Commonwealth.
- (5) The Board may issue a certificate after the Board's review of:
  - (a) The applicant's application and accompanying affidavit;
  - (b) The applicant's qualifications;
  - (c) The applicant's patient records; and
  - (d) Any other pertinent documents or information, including, but not limited to, patient complaints which may affect the applicant's ability to safely and effectively treat patients under anesthesia and sedation.
- (6) A certificate issued under this regulation is not specific to a particular practice location.
- (7) A certificate expires on December 31 of the odd numbered year following the effective date of the certificate.
- (8) A dentist who administers anesthesia or sedation pursuant to this regulation shall maintain the appropriate permit for the administration site.
- (9) Before the certificate expires, an applicant may apply to renew the certificate for an additional two (2) year term if the applicant submits to the Board:
  - (a) An "Application for Renewal of a Certificate to Provide Treatment Outside the Dentist's Location";
  - (b) An affidavit indicating whether the applicant, since the issuance of the original certificate or renewal, whichever is later, has treated a patient under deep sedation or general anesthesia with an incident;
  - (c) The fee required by administrative regulation; and
  - (d) Any other pertinent documents or information requested by the Board.
- (10) An affidavit provided to the Board under Subsection (9)(b) of this section, which indicates that the applicant has treated a patient under deep sedation or general anesthesia with an incident, shall include the information contained in Section (6)(7) of this regulation.
- (11) The Board may issue a renewal certificate to a dentist after the Board's review of:
  - (a) The applicant's application and accompanying affidavit;
  - (b) The applicant's qualifications; and
  - (c) Any other pertinent documents or information, including, but not limited to, patient complaints which may affect the applicant's ability to safely and effectively treat patients under anesthesia and sedation.

### Section 29. Administration by a Certified Registered Nurse Anesthetist.

- (1) A treating dentist who wishes to allow a certified registered nurse anesthetist to administer anesthesia and sedation to a patient at a specific practice location shall receive a certificate from the Board before allowing a certified registered nurse anesthetist to administer anesthesia and sedation at that location.
- (2) To apply for a certificate to allow a certified registered nurse anesthetist to administer anesthesia and sedation, a treating dentist shall:
  - (a) Submit an "Application to Allow Administration by a Certified Registered Nurse Anesthetist";

- (b) Provide an affidavit to the Board indicating whether the treating dentist has ever treated a patient under deep sedation or general anesthesia with an incident;
- (c) Submit any other pertinent documents or information requested by the Board; and
- (d) Pay the fee required by administrative regulation.
- (3) An affidavit provided to the Board under Subsection (2)(b) of this section, which indicates that the applicant has treated a patient under deep sedation or general anesthesia with an incident, shall include the information contained in Section (6)(7) of this regulation.
- (4) In addition to the requirements in Subsections (1) through (3) of this section, a treating dentist who applies for a certificate to allow a certified registered nurse anesthetist to administer anesthesia and sedation to a patient shall maintain permits as follows:
  - (a) A treating dentist who allows a certified registered nurse anesthetist to administer moderate enteral sedation to a patient shall maintain a Class I permit for the administration site;
  - (b) A treating dentist who allows a certified registered nurse anesthetist to administer moderate parenteral sedation to a patient shall maintain a Class II permit for the administration site; and
  - (c) A treating dentist who allows a certified registered nurse anesthetist to administer deep sedation or general anesthesia to a patient shall maintain a Class III permit for the administration site.
- (5) In addition to the requirements of this regulation, a dentist who allows a certified registered nurse anesthetist to administer anesthesia and sedation shall maintain facility equipment in the facility consistent with a Class III permit as outlined in Section 9(1) of this regulation.
- (6) The Board may issue a certificate to a dentist to allow a certified registered nurse anesthetist to administer anesthesia and sedation after the Board's review of:
  - (a) The applicant's application and accompanying affidavit;
  - (b) The applicant's qualifications;
  - (c) The applicant's patient records; and
  - (d) Any other pertinent documents or information, including, but not limited to, patient complaints which may affect the applicant's ability to safely and effectively treat patients under anesthesia and sedation.
- (7) A certificate issued to a treating dentist to allow a certified registered nurse anesthetist to administer anesthesia and sedation at a specific location expires on December 31 of the odd numbered year following the effective date of the certificate.
- (8) Before the certificate expires, an applicant may apply to renew the certificate for an additional two (2) year term if the applicant submits to the Board:
  - (a) An "Application to Renew a Certificate to Allow Administration by a Certified Registered Nurse Anesthetist";
  - (b) An affidavit indicating whether the applicant, since the issuance of the original certificate or renewal, whichever is later, has treated a patient under deep sedation or general anesthesia with an incident;
  - (c) The fee required by administrative regulation; and
  - (d) Any other pertinent documents or information requested by the Board.

- (9) An affidavit provided to the Board under Subsection (8)(b) of this section, which indicates that the applicant has treated a patient under deep sedation or general anesthesia with an incident, shall include the information contained in Section (6)(7) of this regulation.
- (10) The Board may issue a renewal certificate to a dentist to allow a certified registered nurse anesthetist to administer anesthesia and sedation after the Board's review of:
  - (a) The applicant's application and accompanying affidavit;
  - (b) The applicant's qualifications; and
  - (c) Any other pertinent documents or information, including, but not limited to, patient complaints which may affect the applicant's ability to safely and effectively treat patients under anesthesia and sedation.

Section 30. Display and Location of Permit. Any permit or certificate issued under this regulation shall be prominently displayed in each facility it is authorized for use in.

# Section 31. Morbidity and Mortality Reports.

- (1) A dentist shall report to the Board, in writing, any death caused by or resulting from the dentist's administration of anxiolysis, moderate sedation, deep sedation, or general anesthesia within seven (7) days after its occurrence.
- (2) A dentist shall report to the Board, in writing, any substantially disabling incident caused by or resulting from the dentist's administration of anxiolysis, moderate sedation, deep sedation, or general anesthesia within fifteen (15) days after its occurrence.
- (3) The written report to the Board required in Subsections (1) and (2) of this section shall include:
  - (a) The date of the incident;
  - (b) The name, age, and address of the patient;
  - (c) The patient's original complete dental records;
  - (d) The name and license number of the licensee and the name and address of all other persons present during the incident;
  - (e) The address where the incident took place;
  - (f) The preoperative physical condition of the patient;
  - (g) The type of anesthesia and dosages of drugs administered to the patient;
  - (h) The techniques used in administering the drugs;
  - (i) Any adverse occurrence including:
    - 1. The patient's signs and symptoms;
    - 2. The treatment instituted in response to adverse occurrences;
    - 3. The patient's response to the treatment; and
    - 4. The patient's condition on termination of any procedures undertaken; and
  - (j) A narrative description of the incident including approximate times and evolution of symptoms.
- (4) The duties outlined in Subsections (1) through (3) of this section apply to every dentist whether or not the dentist holds a permit.